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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/995,304 | 11/27/2001 | Robert H. Kraus JR. | S-94,769 | 8960 |
| 35068 | 7590 | 12/01/2005 | EXAMINER | |
| UNIVERSITY OF CALIFORNIA LOS ALAMOS NATIONAL LABORATORY P.O. BOX 1663, MS A187 LOS ALAMOS, NM 87545 | | | DO, PENSEE T | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1641 | | |

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/995,304 | KRAUS ET AL. |
| | Examiner | Art Unit |
| | Pensee T. Do | 1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 September 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 17-63 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) 15, 16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Amendment Entry & Claims Status

The amendment filed on September 14, 2005 has been acknowledged and entered.

Claims 1-16 are being examined.

Claims 17-63 are withdrawn from further consideration.

Rejection(s) Withdrawn

Rejection under 112, 2nd paragraph is withdrawn herein.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Miltenyi (US 5,543,289).

Miltenyi teaches a process for conducting of high gradient magnetic separation (HGMS). Superior superparamagnetic particles, coated with a polymer such as a polysaccharide or polystyrene, can be prepared in uniform compositions with homogeneous magnetizations. The coating can be conjugated to specific binding moiety complementary to a biological material whose purification or separation is

desired. Then magnetization of the particles is measured. Magnetization means the magnetic moment per volume of the magnetic particles. Identical magnetic field for all the particles in the mixture is imposed. The superparamagnetic particles range from 0.04 um to 0.1 um in size. (see claim 1). Target biological materials are proteins, cells, viruses, bacteria, yeasts, glycoproteins, etc. (see col. 9, lines 6-21). Any number of components in a biological mixture can be labeled with particles of differing magnetizations by treating each homogeneous composition of particles with a different specific binding moiety complementary to a chosen component of the mixture. Each component will then uniquely react with one representative composition of a particular magnetization. The labeled mixture, when subjected to HGMS results in a chromatographic pattern of components separated according to the magnetization of the particles with which they are conjugated. (see col. 11, lines 54-65). Miltenyi also teaches that the superparamagnetic particles can be subjected to HGMS at any stage of its preparation process-before or after coating and before or after size preparation. The prepared particles are applied to HGMS apparatus and fractionated according to magnetic susceptibility). This teaching would apply to the limitation of claim 3- passing the magnetic microspheres through a magnetic field prior to the initial separation stage.(see col. 7, lines 55-62). Coating of the polymeric material around the microcrystals is the same as imbedding and immobilizing microcrystals on the surface of or within an organic polymeric material or glass because the polymeric coating also attaches to the magnetic crystals through the reactive group.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miltenyi (US 5,543,289) in view of McDevitt et al. (US 6,649,403).

Miltenyi has been discussed above.

However, Miltenyi fails to teach the magnetic particles are selected from the group consisting of iron-cobalt, iron-platinum and samarium-cobalt.

McDevitt teaches assay and system for rapid characterization of multi-analyte fluids using magnetic particles comprising of magnetic materials such as samarium-cobalt. (see col. 114, lines 28-46).

It would have been obvious to one of ordinary skills in the art to use the magnetic material such as samarium-cobalt as taught by McDevitt in the method of Miltenyi since samarium-cobalt can be incorporated in colloidal particles. Samarium-cobalt is a rare-earth magnetic material which exhibits maximum magnetic property.

Response to Arguments

Applicant's arguments filed on September 14, 2005 have been fully considered but they are not persuasive.

Regarding the rejection under 102(b) by Miltenyi, Applicants submit that Miltenyi does not teach a method in which magnetic microspheres pass through a magnetic field into a chamber to a collector. Instead, Miltenyi teaches the introduction of particles into a chamber disposed between the poles of a magnet (i.e. within a magnetic field) and filled with a field intensifying matrix that collects the magnetized particles. The magnetic particles are retained on the matrix within the chamber 11 and therefore, within the magnetic field and do not pass through the magnetic field. As the reference states in column 10, lines 45-47, "when the magnetic field is applied, the gradient is created and suitably magnetically labeled samples are retained in the chamber."

Miltenyi teaches that the magnetic microspheres retained in the chamber (within the magnetic field) are eventually eluted from the chamber (see col. 10, lines 48-60). Thus, the retained magnetic microspheres are eventually passed through the chamber or the magnetic field. Thus, Miltenyi still applies to the present invention. It is inherent that the magnetic particles are passed through a chamber and a collector because when the retained microspheres are eluted, there must be some kind of chamber or container to hold and collect the microspheres flowing exiting through the exit 15 of fig. 1.

Since Miltenyi still applies to the present invention, the 103 rejection still remains. No further discussion is necessary.

Allowable Subject Matter

Claims 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
November 22, 2005

Long Le
LONG V. LE
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11/25/05